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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,804	10/25/1999	DAVID G. GORENSTEIN	122144-1001	1041

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/425,804

Applicant(s)

GORENSTEIN ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 18-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to applicant's election with traverse

1. Applicant's election with traverse of Group IV, claims 15-17 in Paper No. 21 and of SEQ ID NO:39 in paper no. 24 is acknowledged. The traversal is on the ground(s) that examiner failed to provide reasons why Groups II, IV, V, VI and VIII are distinct in view of their identical classification. In response, applicant's attention is directed to page 5 of the Restriction mailed August 27, 2002 wherein the examiner points out that the invention groups encompass multiple sequence species which are identified and listed for applicant's convenience of election and wherein the examiner states that the species differ in structure and function and therefore are patentably distinct. Although no further explanation is required, the present examiner offers the following guideline:

Nucleotide sequences encoding different proteins are structurally and functionally distinct chemical compounds unrelated to one another as are the proteins they encode. Absent evidence to the contrary, these sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claims shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141.

That the sequences differ in nucleotide sequence places an initial search burden on the examiner because each one must be searched individually. In addition, the different functions, e.g., the different proteins to which the aptamers bind, must be searched in their appropriate contexts. It is curious that applicant complains of too little detail in the Restriction yet offers no explanation for the contention that "both the sequence and the modifications, alone and in combination, [that] are the invention. Examination of both

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aspects, alone and in combination, will be required to demonstrate the patentability of the present invention" (page 3 of applicant's Response, last paragraph). Furthermore, the Restriction does not separate the sequence and the modifications. Applicant is advised, in this regard, that claimed invention aptamers which have the same function, i.e., bind the same protein, and the same nucleotide sequence but differ only in the position of the thiophosphate modifications, may be claimed as a species. SEQ ID NOS:32, 38, 39 and perhaps others appear to fall in this category.

The restriction requirement is still deemed proper and is therefore made FINAL. Claims 1-14 and 18-39 have been withdrawn from prosecution.

Priority claim

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(a) Claims 15-17 are confusing in containing non-elected subject matter. The claims should be rewritten to recite only elected subject matter, i.e., aptamers which are specific for NF- κ B and are essentially homologous to SEQ ID NO:39 and other SEQ ID sequences having nucleotide sequences identical to that of SEQ ID NO:39. The recitation of one of claim 15 a), b), c) and d), applied to SEQ ID NO:39, may be included.

(b) The phrase "constituents thereof" in claim 15 renders claim 15-17 indefinite because "constituents thereof" is not defined by the claim, the specification does not provide a standard for ascertaining its meaning, and one of ordinary skill in the art therefore would not be reasonably apprised of the scope of the invention. Furthermore, it is not clear whether constituents of "NF- κ B" or constituents of "aptamer" are intended. It is suggested to delete the phrase or define it in the claim with clarification of its antecedent basis.

Prior art of interest

4. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 92/14843 to Gilead Sciences, Inc. discloses aptamers specific for biomolecules wherein the aptamers have therapeutic and diagnostic applications. For therapeutic uses in particular, aptamers may be modified with "substitute" internucleotide linkages including thioate and dithioate linkages which increase stability toward nucleases and confer cell permeation ability. The prior art is replete with teachings of oligonucleotides with dithiophosphate modifications especially for antisense and aptamer pharmaceutical preparations, for example, as in the work of the Larry Gold group cited by applicant.

Conclusion

5. **No claim is allowed.** However, the claims are free of the prior art.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.



Stephanie Zitomer, Ph.D.

March 10, 2003

STEPHANIE W. ZITOMER
PRIMARY EXAMINER